UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA,
ex rel. JOHN R BORZILLERI, M.D. et al.,

Plaintiffs,

vs.

BAYER HEALTHCARE
PHARMACEUTICALS, INC., et. al.,

Defendants.

Civil Action No.
14-CV-031-WES-LDA

REVISED DECLARATION OF JOHN R. BORZILLERI, M.D. IN SUPPORT OF RELATOR'S OPPOSITION TO THE GOVERNMENT'S MOTION TO DISMISS PURSUANT TO 31 U.S.C § 3730(c)(2)(A)

I, John R. Borzilleri, M.D. pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am the Relator in the *qui tam* False Claims Act ("FCA") case before this Court, as well as the Relator in another *qui tam* action pertaining to Medicare Part D "service fees" now pending in the Southern District of New York (SDNY). I make this declaration in opposition to the Government's motion pursuant to 31 U.S.C. § 3730(c)(2)(A) to dismiss Relator's *qui tam* claims.

A. Relator's Contact with the Department of Justice Prior to *Qui Tam* filing.

2. On October 22, 2013, through my attorney, Paul Barone, I initiated contact via email with the Department of Justice (DOJ) regarding a potential *qui tam* filing regarding "service fee" abuse between certain drug manufacturers and pharmacy benefit managers (PBMs) in the Medicare Part D program. Mr. Barone's email included my resume and a nineteen (19) page summary report I wrote which discussed my investigative findings. The email was sent to Sara Bloom at DOJ in the District of Massachusetts (D-MA), as well as Andy Mao and Edwin Winstead at the DOJ Civil Division in Washington, DC. The same day, Ms. Bloom replied that "we would be happy to talk". A call was set up for the next day, October 23, 2013, at 1pm.

3. On the October 23, 2013 call, Mr. Barone and I discussed the findings of my investigation with Ms. Bloom and George Henderson from the D-MA DOJ office. Mr. Henderson quickly stated that he saw the allegations as primarily a potential "kickback" case. We also discussed my recent attendance at an industry conference where a wide array of industry insiders verified the scheme in detail. At the close of the call, we agreed to send DOJ more information for review. Just before 5pm on October 23, 2013, Mr. Barone

forwarded the same recipients a one hundred-five (105) page investigative report, which I wrote, as well as the agenda and conference slides from the "Fair Market Value (FMV) of Bona Fide Service Fee (BFSF)" conference I attended on October 7-8, 2013 in Philadelphia. The investigative report included my extensive first-hand commentary from conference presenters and attendees.

4. On November 13, 2013, Mr. Henderson from the D-MA DOJ emailed Mr. Barone and I that "we have reviewed the information you sent us, and I can give you my impressions." We had a conference call with Ms. Bloom and Mr. Henderson the next day, November 14, 2013. We discussed details of my investigation, with DOJ again reiterating the "kickback" focus of the allegations. During the call, the D-MA referred us to Zachary Cunha, a recent D-MA colleague who was transferring to the District of Rhode Island (D-RI). Mr. Barone emailed Mr. Cunha on November 19, 2013. Mr. Barone and I had an initial phone discussion with Mr. Cunha on November 22, 2013.

5. Counsel Paul Barone and I had a conference call with D-RI AUSA Zachary Cunha on December 12, 2013. We requested the call to discuss some of our concerns about the upcoming *qui tam* filing. I expressed my concern about my non-insider status and my lack of access to closely-guarded Defendant information, such as "service fee" contracts. Mr. Cunha allayed my concerns by saying that I should "not worry". He said in its investigation, the Government "will get the contracts, see how much they (i.e., the PBMs) are getting paid and what they are getting paid for." He said it "should be a very quick investigation". Based upon this feedback, my counsel and I gained comfort that DOJ would aggressively and efficiently investigate the central "kickback" allegations in the case by looking directly at the secretive financial and service transactions/relationships between the Manufacturer and PBM

Defendant parties. My initial *qui tam* case regarding multiple sclerosis (MS) drugs was filed in the D-RI in the first week of January 2014.

B. Relator/Counsel Investigative Meetings/Conference Calls with DOJ.

6. Both my counsel and I participated in all phone calls and meetings discussed below.

7. On June 10, 2014, counsel Regis Shield and I visited the DOJ in D-RI for my Relator interview. In attendance from DOJ D-RI were Zachary Cunha and Richard Meyers. Other attendees included representatives of the FBI and several other federal agencies. The meeting was largely a routine overview of my *qui tam* case, with little discussed beyond the information in the complaint. In the meeting, we did also discuss my extensive unsuccessful efforts to engage federal agencies, and other entities, in investigation of pharmaceutical and PBM business practices in 2013, prior to my uncovering the "service fee" scheme. Mr. Cunha asked me to send him information regarding my pre-*qui tam* efforts. On June 23, 2014, I forwarded via email to Mr. Cunha two versions of the pre-*qui tam* investigative reports written by me in 2013, along with eighty-two (82) pages of my pre-*qui tam* email efforts.

8. On February 27, 2015, counsel Regis Shields and I had a conference call with D-RI AUSA Zachary Cunha and Sanjay Bhambhani from the DOJ Civil Division in Washington, DC. On the call, DOJ informed me for the first of several times that it was having trouble defining a "viable false claims path". They stated that plan sponsor Direct and Indirect Remuneration (DIR) reports did not show any "service fees" in excess of FMV or provide any indication of fraud. I was surprised by these statements because the complaint clearly alleged that the PBM Defendants were NOT reporting these excessive fee payments

to Centers of Medicare and Medicaid Services (CMS), especially in DIR reports. The complaint also clearly stated that the PBM Defendants have many ways to hide payments within subsidiaries (PBM, specialty pharmacy and others), which have no direct Part D reporting requirements. I only got confusing statements from DOJ in reply to these concerns. In addition, DOJ indicated that its investigation was now primarily focused on PBMs, and not the manufacturers. I said that I did not understand this because drug companies, not PBMs, have the clear legal responsibility for the FMV payment of Bona Fide Service Fees (BFSFs) in Medicare Part D. I did not see a legal case against the PBMs alone. I was also aware that, by definition, the central "kickback" allegations were false claims and asked why there seemed to be little focus on "kickbacks" by DOJ. Mr. Cunha responded that "people think it is easy to prove a kickback, but it is actually complex". Finally, due to escalating evidence and accelerating price increases, I informed DOJ that I was considering amending my D-RI complaint to add additional drug products and defendants. Both Mr. Cunha and Mr. Bhambhani discouraged me from doing so. They said it was not necessary. They said that, even if I did amend the D-RI complaint, their investigation would remain focused on the multiple sclerosis drugs in the initial filings. This conference call was quite concerning, providing clear evidence that the DOJ investigation of my *qui tam* case was deficient.

9. On September 25, 2015, counsel Edward Roy and I had an update call with D-RI AUSA Zachary Cunha, at his request. On the call, Mr. Cunha informed us that the Government was "unlikely" to intervene in the D-RI *qui tam* case primarily because CMS was not "supportive". Mr. Cunha said that CMS viewed the allegations as a "regulatory issue" that was not amenable to being addressed by the False Claims Act. I said that if CMS viewed it as a regulatory issue and not fraud, "that was fine" – then they should fix the

problem in order to stop more harm. I did not get a reply to that statement. Mr. Cunha also said that subpoenas were on "hold" in the D-RI case, pending further discussions with CMS. I further stated that I was not surprised that CMS was not supportive due the severe CMS regulatory and oversight deficiencies discussed in the complaints. Mr. Cunha responded that CMS was his "client". I said I thought the "American public" was his client in the case. Mr. Cunha then said that he hoped to make a "non-intervention decision soon" so that he could get "out of the way", in "a matter of months" so that I could pursue the matter as a "public policy" concern, if I so desired. As the call closed, I told Mr. Cunha that I had nearly completed drafting a second *qui tam* action and remained open to filing an amended complaint in D-RI. I did not get a direct reply. I said I would send him a draft of the document and hoped to get some feedback. The document was sent to him via email on September 28, 2015. I did not get a reply to the email or any feedback from Mr. Cunha. On October 6, 2015, I filed a second *qui tam* action in Southern District of New York (SDNY).

10. My frustration that DOJ was not investigating the central "kickback" allegations in the *qui tam* case began to escalate. On a conference call on September 30, 2016 or March 28, 2017, I pursued the following direct line of questioning with D-RI AUSA Zachary Cunha:

> **Dr. Borzilleri:** "So, based on the contracts you have reviewed, you have confirmed that the majority of "service fee" arrangements are structured as "percent of revenue", linked to drug "list" prices and price increases?
>
> **AUSA Cunha:** Yes/confirmed.
>
> **Dr. Borzilleri:** And we know that for most of the Defendant MS drugs that prices and US sales have greatly increased, while prescription volume has been plummeting?
>
> **AUSA Cunha:** Yes/confirmed.
>
> **Dr. Borzilleri:** So then, the PBMs are getting huge increases in "service fees" while

patients treated, prescription volume and related service support needs are sharply declining?

AUSA Cunha: Yes/confirmed.

Dr. Borzilleri: So, if these massive fee payments are not "kickbacks", what is a "kickback"?

AUSA Cunha: No reply.

11. On February 16, 2016, counsel[1] and I attended my Relator interview at the SDNY office in New York City. In attendance at the meeting from SDNY DOJ were Rebecca Martin, Cristine Phillips and Li Yu. In addition, DOJ staff from the D-RI participated over the phone. The meeting was largely a routine overview of my recent SDNY *qui tam* allegations, with little discussed outside the information in the complaint. Near the end of the meeting, counsel asked Ms. Martin about the potential for transferring the case back to D-RI. Ms. Martin curtly replied: "Oh, that is not going to happen." There was no further discussion of the issue. As the meeting was closing, my counsel and DOJ discussed cooperation in promptly formulating Civil Investigative Demands (CIDs) to be served on the SDNY Defendants.

12. On August 9, 2016, counsel Brian Reilly and I had a call with D-RI AUSA Zachary Cunha and Sanjay Bhambhani from DOJ Civil Division in DC. On the call, DOJ reiterated that the majority of "service fee" contracts were structured as a "percent of revenues, based on "list" prices. Mr. Cunha also admitted that these contract arrangements were not protected by the Group Purchasing Organization (GPO) safe harbor. DOJ again reiterated, to my disappointment, that DIR reports were a central focus of their investigation.

[1] I attended the SDNY Relator interview with experienced *qui tam* counsel that was "evaluating" my cases. In early March 2016, I informed this counsel that I decided against enlisting their representation.

I also asked DOJ whether they were still investigating the drug manufacturers. I said that I was concerned because a recent SEC filing by Defendant Biogen stated that the company had responded to DOJ D-RI subpoenas and expected no further involvement. DOJ claimed that the manufacturer investigation was still ongoing, and that DOJ had "no control" over the Defendants' Security and Exchange Commission (SEC) disclosures. I found this commentary concerning and potentially inaccurate. As a long-standing professional equity analyst, I knew that Biogen's SEC claim was unlikely without Government input. On the call, I also queried DOJ regarding their investigation of the Catastrophic Subsidy allegations. To my surprise, they stated that they "had not thought it through", without any additional commentary. DOJ admitted that they had not issued subpoenas specific to the Catastrophic allegations. Finally, Mr. Cunha admitted that he had not spoken to any witnesses I had provided from the October 2013 FMV conference.

13. On September 30, 2016, counsel Brian Reilly and I had a conference call with D-RI AUSA Zachary Cunha. On the call, Mr. Cunha agreed that the Defendants "service fee" contracts were not protected by the Group Purchasing Organization (GPO) AKS safe harbor. He again admitted that most "service fee" contracts were based on a "percent" of revenue linked to AWP or WAC prices. He also admitted that the "basket" of services provided by the PBM Defendants was largely the same for all. He said it was a "static basket" of services. He admitted that he had not spoken to any "lawyers" from the October 2013 FMV conference. He said that he that he had spoken to one of the consulting firms at the FMV conference, and it "almost put them out of business".

14. On March 28, 2017, counsel Brian Reilly, counsel Eric Renner and I had an updated conference call with D-RI AUSA Zachary Cunha related to a DOJ investigation

extension request. On the call, Mr. Cunha informed us that the D-RI was in "increasingly close communication with SDNY". He said that the DOJ in RI was no longer awaiting any information from the Defendants, but they were not "ready to make a decision" about the case yet. He said that the D-RI and SDNY were planning to make their intervention decisions regarding the two *qui tam* cases at the same time. He said the decision was "long since past due". Mr. Cunha said that he "had not looked at" the Part D Catastrophic allegations but said DOJ did not see "factual support" for it. Regarding Relator's Catastrophic allegations, Mr. Cunha stated that "they had enough on their plate with other allegations." Mr. Cunha informed us that the DOJ in D-RI had done some "witness interviews" in its *qui tam* investigation, but that none of them were "under oath". He also informed us that DOJ would not involve us in evaluation of any evidence and that we would never see any of the government information from its investigation, either before or after its intervention decision.

15. On March 31, 2017, counsel Brian Reilly and I had an update conference call with SDNY AUSAs Cristine Phillips and Li Yu related to a DOJ investigation extension request. On the call, DOJ admitted that the "service fee" contracts between the Manufacturer and PBM Defendants were routinely structured as "percent of revenue tied to list price increases." They informed us that they had received a lot of "specific" information from the Manufacturer Defendants and were not waiting for any more from them. They said they were still awaiting information from the PBM Defendants, but some of them, especially Express Scripts, were resisting providing it. On the call, DOJ admitted that no one had been deposed to date in either the SDNY or D-RI investigations, including anyone from the October 2013 FMV conference. They informed us that CMS viewed the allegations as a

"regulatory issue" and was not supportive of the investigation. They said it was best to go to CMS with "specific" facts and that Ms. Phillips viewed my allegations as an "abstract theory". I responded that I did not think there was anything abstract about the fee scheme nor the severe harm it was causing a lot of Americans.

16. In a conference call with counsel Brian Reilly and myself on August 17, 2017, SDNY AUSA Cristine Phillips informed us that they did not see "anything" from the Manufacturers that was a "False Claims Act violation". Overall, they had "not found data that allowed a False Claims Act action". Regarding pursuit of the Catastrophic Subsidy allegations, Ms. Phillips said, "it had not borne out in the data", without additional commentary. She said there was still "more work" regarding the PBMs. She said they planned to take "some depositions from the PBMs" and were still awaiting some documents. She said that DOJ was not looking to "flip" anyone in a deposition. I had no idea what she meant by the latter statement. At the close of the call, we discussed logistics if DOJ made a non-intervention decision. Finally, I asked her, if the "service fee" scheme was not the cause of the drug price increases, why were they going up? Ms. Phillips responded, "because they can" and that finding other explanations was not part of DOJ's investigation. Ms. Phillips admitted that "CMS was not helpful". She said that she had only reviewed data from the Defendants, not data from CMS. She said there were "lots of agency concerns" and that you "must have agency on board". She said there have been "very few cases" that went forward when CMS was not supportive. I asked her about the potential false claims path basis for the pursuing the PBMs alone, given that the manufacturers bore the primary legal responsibility for the FMV of Bona Fide Service Fees (BFSFs). I did not get a direct response. I asked her how she could be sure of the accuracy of the Defendant data without verifying the data with CMS. I did not get a direct

reply.

17. Over the final 6-8 months of its investigation, DOJ informed Relator that the SDNY and D-RI focus was on coordinating a deposition from a single employee of Defendant Express Scripts. DOJ in both jurisdictions admitted that no other Defendant employees were deposed in the more than 4+ years of investigation of Relator's *qui tam* actions. The single Express Scripts deposition was delayed several times due to scheduling difficulties with Express Scripts. As per DOJ, the deposition reportedly occurred in late January 2018, after both jurisdictions had already made it clear to Relator and counsel that the Government was not going to intervene in either matter. DOJ would not identify the Express Scripts employee nor provide any feedback related to the deposition. DOJ filed its non-intervention decisions regarding both matters in early March 2018.

18. On March 8, 2018, counsel Mary Ann Smith and I had a final conference call with AUSA Cristine Phillips in SDNY DOJ, in which she informed us that the Government had made a non-intervention decision in the SDNY *qui tam* matter. I asked her for the rationale for the non-intervention decision. Her only specific commentary was that the Government felt that the Manufacturer and PBM "service fee" contractual arrangements were protected by the Group Purchasing Organization (GPO) anti-kickback safe harbor. Based upon information in the complaint and additional investigative information provided to DOJ SDNY, I immediately knew Ms. Phillips rationale for non-intervention lacked merit. I then asked Ms. Phillips why the Government non-intervention filing with the Court requested unsealing a month after the non-intervention decision, rather than immediately. She said that the Government generally wanted to give the Relator time to consider their options, including voluntarily dismissing the case. She said we might consider dismissal because DOJ had looked "under every rock" in

investigating the case.

C. Relator/Counsel Contact with DOJ Regarding Case Transfer/Consolidation.

19. After no contact from DOJ following its March 2018 non-intervention decisions in both *qui tam* matters, D-RI AUSA Zachary Cunha sent an email to my D-RI attorneys, Edward Roy and Mary Ann Smith on August 31, 2018. Mr. Cunha requested: "a quick call with you regarding logistics to ensure that the litigation proceeds in a way that does not unduly burden the United States or the parties, or that compromises interests of judicial economy." In the email, Mr. Cunha cc'd Li Yu from DOJ in SDNY and Sanjay Bhambhani from the DOJ Civil Division in DC. A conference call was held on September 4, 2018, including all three of these DOJ staff, my two attorneys and me. The call was very brief, lasting only 5-10 minutes. Counter to SDNY DOJ Li Yu's Declaration related to this motion, DOJ did not ask us to "consent" to transferring one of the cases. Rather, DOJ asked whether we would "consider" transferring or consolidating one of the cases. On call, DOJ was unwilling to discuss any further details related to a potential transfer/consolidation, including logistics, timing, jurisdictional issues, etc. DOJ admitted that they had not contacted either the D-RI or the SDNY Court or any Defendants regarding a potential transfer. The call ended very quickly with us agreeing to "consider" transfer/consolidation and reply to DOJ promptly. Right after the call, I discussed the DOJ request with both my counsel in a conference call. We all agreed that both the timing and nature of DOJ's request was very odd, given the lack of communication from DOJ in the more than 6 months since their non-intervention decisions and the efficient progression of both *qui tam* matters in the respective Courts. We also found it concerning that DOJ had not contacted either the Defendants or the Court. Over the next week, we carefully considered case issues/complexities related to a potential transfer. We concluded

that transfer of one of the cases at this late stage could be very disruptive, leading to the use of escalating resources for all parties, including the Defendants and the Courts. We thought it best to continue with the efficient Court schedules for each separate matter at the present time. We agreed we would be open to considering transfer/consolidation of one of the matters in the interest of judicial economy, if the Courts thought it appropriate. At my request, Mr. Roy informed Mr. Cunha of our decision by email on September 14, 2018. Neither Mr. Roy nor Ms. Smith received further communication from DOJ thereafter about a potential transfer/consolidation.

20. I declare under penalty of perjury that the forgoing statements are true and correct to the best of my knowledge and belief.

Dated: January 11, 2019

John R. Borzilleri, M.D.
Relator

State of New York)
County of Suffolk)

On the 12 day of January in the year 2019, before me, the undersigned notary public, personally appeared John Borzilleri, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is (are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

EVAN R. GRAVANO
NOTARY PUBLIC, STATE OF NEW YORK
NO. 01GR6382671
Qualified in Suffolk County
Term Exprires October 29, 2022

Notary Public